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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,327	02/24/2004	Paul J. Sheskey	63633	9686

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The Dow Chemical Company
Intellectual Property Section
P.O. Box 1967
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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
08/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,327	SHESKEY ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2009 has been entered.

Election/Restrictions

To summarize the election of record, applicant elected Group I drawn to processes for dispersing fluids in a mass of solid particles.

NEW REJECTIONS

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 21 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828 (hereafter patent '828') in view of Rudnic et al. (see below for citation) Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where particles are agglomerated by being contacted with foam and then mixed. While the particle size recited by patent '828 is 1 mm to 25 mm and that of the instant claim is less than 1000 microns, routine experimentation by one of ordinary skill in the art based upon the teachings of patent '828 would render this limitation obvious. Patent '828 teaches cellulose esters and poly(vinylpyrrolidone) as the polymer included in the foam which are both known binders in the pharmaceutical art (see Rudnic et al. claim 8) and meet the limitation of the instantly claimed binder. Therefore claim 1 is obvious over claims 1-2 of U.S. Patent No. 7,070,828.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parikh et al. (previously cited) in view of Lopez (previously cited), and as evidenced by Rudnic et al. (US Patent No. 5,484,608).

Parikh et al. teach the coating of drug containing particle cores that are 80 to 300 micrometers in size (see paragraph 34; instant claims 21 and 24-25). Parikh et al. go on to teach both a taste masking and texture masking coating that are utilized in the

invention (see paragraphs 20-21 and 35). This coating is also taught to cover the entire surface of the core (see paragraphs 32 and 35). An embodiment of a texture masking composition teaches an aqueous solvent in the form of ethanol and water that constitutes 90 wt% (as calculated by the examiner) of the coating preparation and also includes hydroxypropylmethylcellulose (see example 2). Rudnic et al. teach that hydroxypropylmethylcellulose was a known pharmaceutical binder (see claim 8; instant claim 21). The coating process is taught to occur in a fluidized bed or rotary coater (see paragraph 43). The resulting particles are a granular material. After production of these coated particles, Parikh et al. teach the production of larger granules (agglomeration) (see paragraph 56; instant claims 21). Thus at the end of the processing steps of Parikh et al. agglomerated particles are the result. Although Parikh et al. teach that several methods can be used to coat the particle cores, they do not teach coating by application of a foam (see paragraphs 43 and 52).

Lopez teaches a process of coating pharmaceutical solid forms (see column 1 lines 6-8). Lopez teaches that the process of coating solid forms by conventional means of dipping, pouring, or spraying often leads to unevenness in the coating layer (see column 1 lines 11-12 and 15-20). In addition, Lopez teaches that spray coating a liquid typically requires high pressures to appropriately atomize the coating medium and poses several challenges to uniform coating (see column 1 lines 46-75). The process taught by Lopez to circumvent the challenges of standard spray coating is amenable to nearly any type of coating medium and results in even and uniform coating, as well as shortened processing times (see column 2 lines 65-66 and 73-75). Lopez teaches the method of introducing air into a coating composition to produce foam that is then

sprayed onto the pharmaceutical solids (see example and column 3 line 72-column 4 line 9; instant claims 21 and 23).

The complete coverage of the drug particles is taught by Parikh et al., thus one of ordinary skill in the art at the time the invention was made would have found it obvious to modify their invention by using the foam coating technique of Lopez to help ensure that complete and uniform coverage of the particles could be achieved. Based upon the recitation of instant claim 21, mixing of the foam components into the particles and agglomeration of the particles yields agglomeration of the solid particles; therefore this limitation is met by the foam coating method of Parikh et al. in view of Lopez. Therefore claims 21 and 23-26 are obvious over Parikh et al. in view of Lopez and as evidenced by Rudnic et al.

Claims 21-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie-Muncy et al. (previously cited) in view of Richardson et al. (US Patent No.6,797,291)

Hardie-Muncy et al. teach the application of a coating to moisture sensitive particulate materials by foaming the coating medium then applying the foam to the particles so as to protect them from exposure to moisture (see abstract and column 1 lines 5-11). In particular, they teach that a binding agent is included at 0.1 to 20% in water to make up the foam composition (see column 2 lines 33-35; instant claim 26). Further, Hardie-Muncy et al. teach that their process forms a foam that is then mixed with the particles to form agglomerates (see column 2 lines 46-57; instant claim 22).

Hardie-Muncy et al. do not explicitly teach that the particles contain therapeutic or recite their size.

Richardson et al. teach hygroscopic (moisture sensitive) bioactive (therapeutic) components (see column 1 lines 7-11). These components are taught to be less than 1000 microns in diameter (see (column 8 lines 35-41; instant claim 21).

Since some bioactive particles are known to be sized less than 1000 microns and also be moisture sensitive, based on Richardson et al., it would have been obvious to one of ordinary skill in the art to use such particles in the process taught by Hardie-Muncy et al. to protect them from undesired moisture and help them retain their desired structure and function. Therefore claims 21-22 and 26 are obvious over Hardie-Muncy et al. in view of Richardson et al.

Response to Arguments

It is noted that applicant has indicated their willingness to file a terminal disclaimer should the instant claims become allowable.

Applicant's arguments filed August 6, 2009 have been fully considered but they are moot in light of the new grounds of rejection.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635